UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Case No.: 7:24-CV-02137-NSR

----------X

ROBERT CROCI, AS ADMINISTRATOR OF THE ESTATE OF JOANN C. CROCI, DECEASED,

Plaintiff

MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

-against-

ZOLL MEDICAL CORPORATION AND ZOLL SERVICES, LLC,

Defendants.

----------X

PRELIMINARY STATEMENT

Plaintiff respectfully submits this Memorandum of Law in Opposition to the motion of Defendants to dismiss this matter.

Plaintiff, in his role as Administrator of the Estate of his deceased wife, brought suit in Supreme Court, Orange County against the Defendants herein, alleging that the death of his wife was the result of Defendant's negligence, products liability and breach of warranty.

The defendant filed a Notice of Removal to this Court. After motion practice, such removal was upheld.

The defendant now contends that this case should be dismissed due to federal preemption and claims that the causes of action alleged fail to state claims upon which relief can be granted in New York State Court. For the reasons set forth below, the Defendants are mistaken in both assertions.

FACTUAL DISCUSSION

Plaintiff takes no issue with the factual background as set forth by the Defendants herein.

STANDARD OF REVIEW

In the context herein, plaintiff's allegations are accepted as true and the complaint is to be construed in the light most favorable to the plaintiff. See Mink v. Smith & Nephew, Inc., 860 F3rd 1319 (11th Circuit 2017) and Godelia v. Zoll, LLC No. 17-10736 (11th Cir., 2018).

PREEMPTION

The Medical Device Amendments of 1976 give the FDA regulatory authority over medical devices. See Mink v. Smith & Nephew, 860 F. 3rd 1319. The life vest is a class III device which is subject to the most stringent regulation.

Under the amendments, there are two types of preemption – express and implied. The express preemption bans an claim based on a state law requirement which is different form or in addition to any requirement under the MDA. 21 USC Sect 360k(a). The implied provision, 21 USC Sect 337 bars claims that merely attempt to enforce duties owed to the FDA.

However, not all claims are barred. See Medtronic v. Lohr, 518 U.S. 470. In that case, the Court made it clear that some state common law claims are capable of surviving the effect of the statute. State common law claims, such as those brought herein, based on defective design and manufacturing, were not preempted to the extent the claims mirrored federal requirements. In Riegel v. Metronic, Inc., 552 U.S. 312, upon which defendants rely, does not support their position. In that case the Court was careful to note that any duties imposed by state law are only preempted to the narrow extent that they add different or extra requirements to the federal scheme. See Riegel at 330. Parallel state duties survive so long as they claim a violation of state tort law that aligns with the federal requirement.

The position that defendant would have the court adopt would mean that no state law claim could ever be brought against it, regardless of how it is pled. But the Supreme Court has already stated that this was not the intent of the MDA. See Medtronics v. Lohr, 518 U.S. 470. It was made very clear in that case that the Court would not accept the perverse proposition that the entire medical device

industry should have complete immunity from tort liability. Particularly as it seemed Congress felt the industry needed more, not less oversight.

The decision being sought by defendants in this matter goes beyond what the amendments provide and seeks immunity to which they are not entitled. In a case such as this, where the plaintiff can demonstrate that he or she was hurt by a manufacturer's breach of a common law duty owed to him and that duty is parallel to the requirements of federal law, there is no preemption.

As set forth in Bausch v. Stryker Corp., 630 F3rd 546 (7th Cir., 2010), the scope of preemption is limited. Lawsuits brought under state law against medical device manufacturers who submit premarket notification to the FDA are not preempted when the liability is premised on theories that the device was defective and unreasonably dangerous and that the manufacturer failed to use reasonable care in the device's design, manufacture, assembly and sale. These are the exact allegations in Plaintiff's first and second causes of action. See Plaintiff's Exhibit A attached to the Declaration of George A. Smith, Esq.

To the extent that defendants claim that even if a common law claim can survive a preemption defense, plaintiff must demonstrate and prove a violation of a concrete and device specific federal regulation, such premise has been rejected in cases such as Bausch v. Stryker, 630 F3rd 546 (7th Cir., 2010) and Howard v. Sulzer Orthopedics, 382 Fed Appx 436 (6th Cir., 2010). There is no sound legal basis to distinguish between general requirements and concrete device specific requirements. Section 360K refers to "any requirement." Not only is the premise the defendants would have the court adopt unworkable and unfeasible, it is in no way supported by the language of the statute.

Defendants' assertion that the complaint is insufficiently pled must fail. The complaint is pled with much more specificity beyond the normal state complaint. And all that is required is that the plaintiff allege sufficient facts to meet the plausibility standard as set forth in Ashcroft v. Iqbal, 556 U.S. 662 and Bell Atlantic Corp. v. Twombly, 550 U.S. 544. To survive a motion to dismiss the complaint must contain sufficient factual matter, **accepted as true**, to state a claim for relief that is plausible on its face.

Further, in applying this standard to claims for defective manufacture of a medical device, it must be kept in mind that much of the product-specific info9rmatin needed to investigate such a claim is confidential and that full discovery will be needed before a plaintiff can fairly be expected to provide a detailed statement of the basis for his or her claim. The causes of action set forth in plaintiff's complaint set forth a number of facts, all of which accepted as true, hold the defendants in liability. This is all that is needed. See Exhibit A to the Declaration of George A. Smith, Esq.

Defendants object that the original complaint does not specify the exact defect or specific regulatory requirements which were allegedly violated. Even if true, such does not support a dismissal under Rule 12(b)(6). There are no special requirements under Rule 9(b) that any such complaint be pled with particularity. Further, see Bennett v. Schmidt, 153 F3rd 516 (7th Cir., 1998)) which held that generally plaintiffs are entitled to discovery before being put to their proof.

Additionally, again, in the context of Class III medical devices, much information is kept confidential, and an injured patient cannot gain access to necessary information without formal discovery. See Medtronic Leads, 623 F. 3rd at 1211. If the problem turns out to be a design feature that the FDA approved, Section 360K will protect defendants. However, if the problem turns out to be a failure to comply with the FDA's legally enforceable conditions for approval of the device, Section 360K will not protect the manufacturer.

For Plaintiff to plead with any more specificity than he already has, he would need access to material to confidential materials in the pre-market approval process which he cannot obtain at this time. It seems defendants want to have their cake and eat it to, which is unfair. If a plaintiff must allege a violation of a specific FDA approved specification before discovery, then simply no plaintiff will ever be able to survive a dismissal motion and we will be back at the perverse situation where the medical device industry is rendered totally immune from tort liability. The plaintiff's burden in pleading should be commensurate with the information available to them.

VALIDITY OF UNDERLYING CLAIMS

The Defense argument that the underlying claims are not sufficient under New York law is, to put it simply, utterly wrong. As the defense correctly notes, Plaintiff set forth four causes of action in its underlying complaint. Each of those causes of action is pled with the requisite specificity under New York Law. Each of those four causes of action sets forth the requisite elements of the individual cause of action under New York law. In fact, Plaintiff's complaint is more detailed and specific than those generally found in such cases. Again, as noted above, without discovery it is difficult to impossible for Plaintiff to be more specific in her claims.

New York law recognizes strict liability claims based on a manufacturing defect. See Voss v. Black and Decker Mfg. Co., 59 NY2d 102 (1983) and Liriano v. Hobart Corp, 92 NY 232 (1998). New York law also recognizes negligence claims in relation to manufacturing defects. See Matter of New York City Asbestos Litigation, 27 NY3rd 765 (2016). Here plaintiff says that Zoll manufactured the life vest and placed it into commerce and that the life vest was defective and nonconforming and that those defects caused the plaintiff's injuries. On its face, this is sufficient to state a claim under New York law for strict liability and negligence related to a manufacturing defect. There is no need to state the precise defect which caused the life vest to malfunction. See Small v. Amgen, 2 F. Supp. 3rd 1292 (M.D., Fla., 2014). The allegations in the complaint are sufficient to state a claim which is plausible on its face. See Iqbal, supra. It is plausible that ZOLL's failure to document and respond to complaints about life vests in violation of 21 CFR 820.198(a) could have resulted in a defect persisting in the life vests long after ZOLL should have been aware of it and that this caused plaintiff's death. Plaintiff's claims herein are sufficiently pled.

Defendants claim that Plaintiff cannot prevail on the warranty claim due to a lack of privity. But that is specious. Even if privity is required for a breach of warranty claim in New York, and the plaintiff

would contend that it is not, the fact remains that the plaintiff had direct contact with ZOLL representatives who came to her home and who examined the life vest which was provided her and "desensitized it". This certainly provides the necessary privity.

All of the causes of action are set forth in the original complaint in such a way that a New York court could not dismiss them on a pre-answer motion. Each one sets forth the elements of the cause of action alleged. Each one sets forth a violation of New York State law parallel to and not preempted by federal law.

CONCLUSION

For all of the reasons set forth above, the causes of action alleged by the plaintiff are not preempted by federal law and are sufficient under New York State law to state a claim. The action should not be dismissed at this early point in the litigation.

Dated: January 30, 2025

Goshen, New York 10924

George A. Smith, Esq.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was served by Email on January 30, 2025 on the following:

Jenny A. Covington, Esq.

Nelson Mullins Riley & Scarborough LLP

1600 Utica Avenue S., Suite 600

Minneapolis, MN 55416

Jenny.covington@nelsonmullins.com

Attorneys for Defendants

George A. Smith, Esq.